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PROPHYLACTIC AGENT FOR DENTAL DECAY
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FOREIGN TITLE (54A): MUSHIBA YOBOZAI

(54) [Title of the Invention] /1*

PROPHYLACTIC AGENT FOR DENTAL DECAY

(57) [Abstract]

[Problem to be Solved]

To obtain a prophylactic agent for dental decay that is safe to the body and has an excellent prophylactic effect on dental decay. [Solution] This prophylactic agent for dental decay consists essentially of at least one or more kinds of metaphosphates such as sodium metaphosphate or potassium metaphosphate and polyphosphates such as sodium polymetaphosphate.

[Translator's note: pages 2, 3 and the top of 4 have been completely amended. The amendments have been incorporated into the body of the text, starting in the middle of page 4.]

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[Amendments]
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[Claims]

[Claim 1] A prophylactic agent for dental decay comprised of at least one or more kinds of metaphosphates and polyphosphates as the essential elements.

[Claim 2] A prophylactic agent for dental decay as claimed in Claim 1 comprised of a phosphate that is either a sodium, calcium or potassium phosphate.

* Number in the margin indicates pagination in the foreign text.

[Detailed Explanation of the Invention]

[0001] [Industrial Field of Application]

This invention relates to a prophylactic agent for dental decay that is safe to the body and is comprised of at least one or more kinds of metaphosphates and polyphosphates as the essential elements. This invention relating to a prophylactic agent for dental decay can be a pharmaceutical, a formulation for dentistry or a food product.

[0002] [Existing Technology]

Tooth decay (cavities) is a disease of the oral cavity that causes pain and destroys crowns so prevention is desirable. The cause of tooth decay (cavities) is due to sugars contained in food residue residing between teeth or in the irregularities of the teeth surface that cause a breakdown of lactic acid due to acid bacteria. This lactic acid action involves hydroxyapatite dissolution, which is comprised of the structural elements of teeth, approximately 95% enamel and approximately 75% dentine.

[0003] Controlling the hydroxyapatite dissolution to prevent tooth decay (cavities) has generally involved either a method of directly applying sodium fluoride to the surface of the teeth or a method of mixing sodium fluoride into dentifrice.

[0004] [Problems this Invention is to Solve]

Sodium fluoride is very toxic to the human body, which is a problem. Specifically, the minimum lethal dose is 4g for humans but chronic poisoning is related to macular dental osteosclerosis.

[0005] Other than the methods of applying sodium fluoride to the surface of the teeth or mixing sodium fluoride into dentifrice, there is no other effective method for preventing tooth decay.

[0006] [Means of Solving These Problems]

This invention takes the information given above into consideration and presents a prophylactic agent for dental decay that is comprised of the essential elements of phosphates that are not harmful to the human body. The invention claimed in Claim 1 is a prophylactic agent for dental decay comprised of at least one or more kinds of essential elements including a metaphosphate and polyphosphate. The invention claimed in Claim 2 is a prophylactic agent for dental decay as claimed in Claim 1 comprised of a phosphate that is either a sodium, calcium or potassium phosphate.

[0007] [Embodiment Examples for this Invention] /5

Next is a detailed description of this invention. The first embodiment example for the prophylactic agent for dental decay relating to this invention is a prophylactic agent comprised of essential elements including a metaphosphate. The metaphosphate can be a trimetaphosphate or a tetrametaphosphate. Depending on the metaphosphate given above, aqueous sodium metaphosphate, potassium metaphosphate or calcium metaphosphate insoluble in water can be utilized. Specific examples include sodium trimetaphosphate, sodium tetrametaphosphate, calcium trimetaphosphate, calcium tetrametaphosphate, potassium trimetaphosphate and potassium tetrametaphosphate. However, the degree of polymerization is not limited and compounds of these are acceptable.

[0008] The second embodiment example for the prophylactic agent for dental decay relating to this invention is a prophylactic agent comprised of polyphosphates as the essential elements. Aqueous sodium polyphosphate, calcium polyphosphate or potassium polyphosphate can be

utilized as the polyphosphate. However, the degree of polymerization is not limited and compounds of any of these are acceptable for use.

[0009] This invention relates to a prophylactic agent for dental decay is comprised of at least one or more kinds of essential elements, specifically metaphosphates and polyphosphates. It is recommended that the prophylactic agent for dental decay be a combination of two or more phosphates.

[0010] As indicated in the Embodiment example later, the prophylactic agent for dental decay comprised of a combination of metaphosphates and polyphosphates prevents the dissolution of hydroxyapatite causing tooth decay, provides an excellent prophylactic effect against tooth decay and can be utilized as a food additive so is extremely safe to the human body.

[0011] Examples of the prophylactic agent for dental decay in this invention include pharmaceuticals, formulations for dentistry or food products. Pharmaceuticals are used for applications on the surface of teeth. In this case, a combination of sodium metaphosphate and sodium polyphosphate dissolved in water can be utilized. The amount to add should be 20-30wt%. Formulations for dentistry include mouthwashes, toothpaste, adhesives for dental treatment and dental cement. If used as a mouthwash, the sodium metaphosphate and sodium polyphosphate diluted in water should be 1-2wt%. If used as a toothpaste, the metaphosphate and polyphosphate should be 3-5wt%. It can also be combined for use as adhesives for dental treatment and dental cement. It is possible to combine metaphosphate and polyphosphate for food products such as chewing gum.

[0012] [Embodiment Examples]

Next, this invention is explained in detail with the embodiment examples and comparative examples.

(Embodiment Example 1)

1.5g of ash-free pulp was compressed and packed into a 35ml hypodermic syringe and combined with 100mg of hydroxyapatite. The hydroxyapatite was a product for chromatography manufactured by Wako Pure Chemical Industries, Limited. 20 ml of a sodium metaphosphate solution was produced to a concentration of 0.5-20% (manufactured by Katayama Chemical Industries, Ltd, $(NaPO_3)_n (n>3)$, where n is the average polymerization). This sodium metaphosphate preparation was combined in a hypodermic syringe for 10 minutes. After removing the agonist, the hydroxyapatite in the hypodermic syringe was rinsed and 20ml of a lactic acid buffer (pH4.2) was added to the hydroxyapatite. It was left for 16 hours and then 10ml of the solution was separated and sent to the Osaka Serum Microbiology Laboratory in Higashi Yodogawa-ku, Osaka where quantitative measurement of the calcium was performed using chelatometric titration. Measurements were conducted on 5 syringes and the average values of 5 syringes were used to calculate the calcium elution in 1000mg of hydroxyapatite. The results are shown in Table 1.

[Table 1]

Calcium Elution (mg)	
Time / concentration of sodium metaphosphate (%)	10 minutes
0	148.44
0.5	106.24
1.0	99.32
2.0	98.60
3.0	95.16
4.0	90.96
5.0	87.80
10.0	84.44
20.0	63.28

[0013] (Embodiment Example 2)

Other than using 20 ml of a potassium metaphosphate solution in a concentration of 0.1-2.0% (manufactured by Katayama Chemical Industries, Ltd, $(NaPO_3)_n(n>3)$, where n is the average polymerization), the hydroxyapatite calcium elution was measured under the same conditions as Embodiment Example 1. The results are shown in Table 2.

[Table 2] /6

Calcium Elution (mg)	
Time / concentration of sodium metaphosphate (%)	10 minutes
1.0	126.60

[0014] (Embodiment Example 3)

Other than preparing a sodium polyphosphate solution in a concentration of 1-5% with a polymerization of 4, (manufactured by Katayama Chemical Industries, Ltd.), and adding it to hydroxyapatite, the hydroxyapatite calcium elution was measured under the same conditions as Embodiment Example 1. The results are shown in Table 3.

[Table 3]

Calcium Elution (mg)	
Time / concentration of sodium polyphosphate (%)	10 minutes
0.5	138.24
1.0	125.76
2.0	125.64
3.0	123.20
4.0	119.00

[0015] A 2% solution of sodium metaphosphate was stored at room temperature for 93, 183 and 365 days. Other than using this 2% solution of sodium metaphosphate, the hydroxyapatite calcium elution was measured under the same conditions as Embodiment Example 1. The measured effectiveness was reduced by hydrolysis of the polymetaphosphate. The results are shown in Table 4.

[Table 4]

Calcium Elution (mg)	
Concentration / Days Stored	2%
93 days	101.28
183 days	105.80
365 days	105.32

[0016] (Comparative Example)

Other than preparing a sodium fluoride solution in a concentration of 0.1-2.0%, the conditions were the same as in Embodiment Example 1. The hydroxyapatite calcium elution was measured and the results are shown in Table 5.

[Table 5]

Calcium Elution (mg)	
Time / concentration of sodium polyphosphate (%)	10 minutes
0.1	114.12
2.0	72.00

The results from Embodiment Examples 1-4 and the Comparative Example show that the prophylactic agent for dental decay in this invention demonstrated an inhibiting effect on hydroxyapatite elution compared to sodium fluoride.

[0017] Next are the formulations of the prophylactic agent for dental decay in this invention.

(Formulation 1)

Applications on the surface of teeth	(%)
sodium metaphosphate	20
water	balance
Total	100

(Formulation 2)

Mouthwashes	(%)
sodium metaphosphate	1
water	balance
Total	100

(Formulation 3)

Chewing gum	(%)
sodium metaphosphate	1
gum base	95
Citric acid	3
Perfume	1
Total	100

The formulations for the prophylactic agent for dental decay in this invention are not limited to those given above.

[0018] [Effect of this Invention]

This invention is a prophylactic agent for dental decay comprised of at least one or more kinds of metaphosphates and polyphosphates as the essential elements. As clearly indicated by Embodiment Examples 1-4 given above, the hydroxyapatite solution that is the primary element in dentine that causes tooth decay is controlled. Thus there is an excellent prophylactic effect on dental decay as well as an excellent effect on the safety to humans.